

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996]

#### § 890.5975 Therapeutic vibrator.

(a) *Identification*. A therapeutic vibrator is an electrically powered device intended for medical purposes that incorporates various kinds of pads and that is held in the hand or attached to the hand or to a table. It is intended for various uses, such as relaxing muscles and relieving minor aches and pains.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996]

## PART 892—RADIOLOGY DEVICES

### Subpart A—General Provisions

Sec.

- 892.1 Scope.
- 892.3 Effective dates of requirement for premarket approval.
- 892.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

### Subpart B—Diagnostic Devices

- 892.1000 Magnetic resonance diagnostic device.
- 892.1100 Scintillation (gamma) camera.
- 892.1110 Positron camera.
- 892.1130 Nuclear whole body counter.
- 892.1170 Bone densitometer.
- 892.1200 Emission computed tomography system.
- 892.1220 Fluorescent scanner.
- 892.1300 Nuclear rectilinear scanner.
- 892.1310 Nuclear tomography system.
- 892.1320 Nuclear uptake probe.
- 892.1330 Nuclear whole body scanner.
- 892.1350 Nuclear scanning bed.
- 892.1360 Radionuclide dose calibrator.
- 892.1370 Nuclear anthropomorphic phantom.
- 892.1380 Nuclear flood source phantom.
- 892.1390 Radionuclide rebreathing system.
- 892.1400 Nuclear sealed calibration source.
- 892.1410 Nuclear electrocardiograph synchronizer.
- 892.1420 Radionuclide test pattern phantom.
- 892.1540 Nonfetal ultrasonic monitor.
- 892.1550 Ultrasonic pulsed doppler imaging system.

- 892.1560 Ultrasonic pulsed echo imaging system.
- 892.1570 Diagnostic ultrasonic transducer.
- 892.1600 Angiographic x-ray system.
- 892.1610 Diagnostic x-ray beam-limiting device.
- 892.1620 Cine or spot fluorographic x-ray camera.
- 892.1630 Electrostatic x-ray imaging system.
- 892.1640 Radiographic film marking system.
- 892.1650 Image-intensified fluoroscopic x-ray system.
- 892.1660 Non-image-intensified fluoroscopic x-ray system.
- 892.1670 Spot-film device.
- 892.1680 Stationary x-ray system.
- 892.1700 Diagnostic x-ray high voltage generator.
- 892.1710 Mammographic x-ray system.
- 892.1720 Mobile x-ray system.
- 892.1730 Photofluorographic x-ray system.
- 892.1740 Tomographic x-ray system.
- 892.1750 Computed tomography x-ray system.
- 892.1760 Diagnostic x-ray tube housing assembly.
- 892.1770 Diagnostic x-ray tube mount.
- 892.1820 Pneumoencephalographic chair.
- 892.1830 Radiologic patient cradle.
- 892.1840 Radiographic film.
- 892.1850 Radiographic film cassette.
- 892.1860 Radiographic film/cassette changer.
- 892.1870 Radiographic film/cassette changer programmer.
- 892.1880 Wall-mounted radiographic cassette holder.
- 892.1890 Radiographic film illuminator.
- 892.1900 Automatic radiographic film processor.
- 892.1910 Radiographic grid.
- 892.1920 Radiographic head holder.
- 892.1940 Radiologic quality assurance instrument.
- 892.1950 Radiographic anthropomorphic phantom.
- 892.1960 Radiographic intensifying screen.
- 892.1970 Radiographic ECG/respirator synchronizer.
- 892.1980 Radiologic table.
- 892.1990 Transilluminator for breast evaluation.
- 892.2010 Medical image storage device.
- 892.2020 Medical image communications device.
- 892.2030 Medical image digitizer.
- 892.2040 Medical image hardcopy device.
- 892.2050 Picture archiving and communications system.

### Subparts C-E [Reserved]

### Subpart F—Therapeutic Devices

- 892.5050 Medical charged-particle radiation therapy system.
- 892.5300 Medical neutron radiation therapy system.

## § 892.1

- 892.5650 Manual radionuclide applicator system.
- 892.5700 Remote controlled radionuclide applicator system.
- 892.5710 Radiation therapy beam-shaping block.
- 892.5730 Radionuclide brachytherapy source.
- 892.5740 Radionuclide teletherapy source.
- 892.5750 Radionuclide radiation therapy system.
- 892.5770 Powered radiation therapy patient support assembly.
- 892.5780 Light beam patient position indicator.
- 892.5840 Radiation therapy simulation system.
- 892.5900 X-ray radiation therapy system.
- 892.5930 Therapeutic x-ray tube housing assembly.

### Subpart G—Miscellaneous Devices

- 892.6500 Personnel protective shield.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 53 FR 1567, Jan. 20, 1988, unless otherwise noted.

### Subpart A—General Provisions

#### § 892.1 Scope.

(a) This part sets forth the classification of radiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a radiology device that has two or more types of uses (e.g., use both as a diagnostic device and a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of this title 21, unless otherwise noted.

## 21 CFR Ch. I (4–1–99 Edition)

#### § 892.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device

before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

**§ 892.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).**

(a) The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(1) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(2) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diag-

nostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(2) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(3) The device is an in vitro device that is intended:

(i) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(ii) For use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism;

(iii) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome

§ 892.1000

21 CFR Ch. I (4–1–99 Edition)

(AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;

(iv) For assessing the risk of cardiovascular diseases;

(v) For use in diabetes management;

(vi) For identifying or inferring the identity of a microorganism directly from clinical material;

(vii) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) and IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;

(viii) For noninvasive testing; and

(ix) For near patient testing (point of care).

[54 FR 13831, Apr. 5, 1989, as amended at 63 FR 59231, Nov. 3, 1998]

Subpart B—Diagnostic Devices

**§ 892.1000 Magnetic resonance diagnostic device.**

(a) *Identification.* A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).

(b) *Classification.* Class II.

[53 FR 5078, Feb. 1, 1989]

**§ 892.1100 Scintillation (gamma) camera.**

(a) *Identification.* A scintillation (gamma) camera is a device intended to image the distribution of radionuclides in the body by means of a photon radiation detector. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class I.

[55 FR 48443, Nov. 20, 1990]

**§ 892.1110 Positron camera.**

(a) *Identification.* A positron camera is a device intended to image the distribution of positron-emitting radionuclides in the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class I.

[55 FR 48444, Nov. 20, 1990]

**§ 892.1130 Nuclear whole body counter.**

(a) *Identification.* A nuclear whole body counter is a device intended to measure the amount of radionuclides in the entire body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 59 FR 63015, Dec. 7, 1994]

[55 FR 48444, Nov. 20, 1990]

**§ 892.1170 Bone densitometer.**

(a) *Identification.* A bone densitometer is a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1200 Emission computed tomography system.**

(a) *Identification.* An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data.

This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1220 Fluorescent scanner.**

(a) *Identification.* A fluorescent scanner is a device intended to measure the induced fluorescent radiation in the body by exposing the body to certain x-rays or low-energy gamma rays. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts and accessories.

(b) *Classification.* Class II.

**§ 892.1300 Nuclear rectilinear scanner.**

(a) *Identification.* A nuclear rectilinear scanner is a device intended to image the distribution of radionuclides in the body by means of a detector (or detectors) whose position moves in two directions with respect to the patient. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class I.

[55 FR 48444, Nov. 20, 1990]

**§ 892.1310 Nuclear tomography system.**

(a) *Identification.* A nuclear tomography system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of devices may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1320 Nuclear uptake probe.**

(a) *Identification.* A nuclear uptake probe is a device intended to measure the amount of radionuclide taken up by a particular organ or body region. This generic type of device may include a single or multiple detector probe, signal analysis and display equipment, patient and equipment sup-

ports, component parts, and accessories.

(b) *Classification.* Class I.

[55 FR 48444, Nov. 20, 1990]

**§ 892.1330 Nuclear whole body scanner.**

(a) *Identification.* A nuclear whole body scanner is a device intended to measure and image the distribution of radionuclides in the body by means of a wide-aperture detector whose position moves in one direction with respect to the patient. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class I.

[55 FR 48444, Nov. 20, 1990]

**§ 892.1350 Nuclear scanning bed.**

(a) *Identification.* A nuclear scanning bed is an adjustable bed intended to support a patient during a nuclear medicine procedure.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device is labeled with weight limit, is used with planar scanning only, and is not for diagnostic X-ray use.

[55 FR 48444, Nov. 20, 1990, as amended at 59 FR 63015, Dec. 7, 1994]

**§ 892.1360 Radionuclide dose calibrator.**

(a) *Identification.* A radionuclide dose calibrator is a radiation detection device intended to assay radionuclides before their administration to patients.

(b) *Classification.* Class II.

**§ 892.1370 Nuclear anthropomorphic phantom.**

(a) *Identification.* A nuclear anthropomorphic phantom is a human tissue facsimile that contains a radioactive source or a cavity in which a radioactive sample can be inserted. It is intended to calibrate nuclear uptake probes or other medical instruments.

§ 892.1380

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 54 FR 13832, Apr. 5, 1989]

**§ 892.1380 Nuclear flood source phantom.**

(a) *Identification.* A nuclear flood source phantom is a device that consists of a radiolucent container filled with a uniformly distributed solution of a desired radionuclide. It is intended to calibrate a medical gamma camera-collimator system for uniformity of response.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 54 FR 13832, Apr. 5, 1989]

**§ 892.1390 Radionuclide rebreathing system.**

(a) *Identification.* A radionuclide rebreathing system is a device intended to be used to contain a gaseous or volatile radionuclide or a radionuclide-labeled aerosol and permit it to be respired by the patient during nuclear medicine ventilatory tests (testing process of exchange between the lungs and the atmosphere). This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1400 Nuclear sealed calibration source.**

(a) *Identification.* A nuclear sealed calibration source is a device that consists of an encapsulated reference radionuclide intended for calibration of medical nuclear radiation detectors.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 54 FR 13832, Apr. 5, 1989]

21 CFR Ch. I (4–1–99 Edition)

**§ 892.1410 Nuclear electrocardiograph synchronizer.**

(a) *Identification.* A nuclear electrocardiograph synchronizer is a device intended for use in nuclear radiology to relate the time of image formation to the cardiac cycle during the production of dynamic cardiac images.

(b) *Classification.* Class I.

[55 FR 48444, Nov. 20, 1990]

**§ 892.1420 Radionuclide test pattern phantom.**

(a) *Identification.* A radionuclide test pattern phantom is a device that consists of an arrangement of radiopaque or radioactive material sealed in a solid pattern intended to serve as a test for a performance characteristic of a nuclear medicine imaging device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 54 FR 13832, Apr. 5, 1989]

**§ 892.1540 Nonfetal ultrasonic monitor.**

(a) *Identification.* A nonfetal ultrasonic monitor is a device that projects a continuous high-frequency sound wave into body tissue other than a fetus to determine frequency changes (doppler shift) in the reflected wave and is intended for use in the investigation of nonfetal blood flow and other nonfetal body tissues in motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1550 Ultrasonic pulsed doppler imaging system.**

(a) *Identification.* An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion. This

generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1560 Ultrasonic pulsed echo imaging system.**

(a) *Identification.* An ultrasonic pulsed echo imaging system is a device intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1570 Diagnostic ultrasonic transducer.**

(a) *Identification.* A diagnostic ultrasonic transducer is a device made of a piezoelectric material that converts electrical signals into acoustic signals and acoustic signals into electrical signals and intended for use in diagnostic ultrasonic medical devices. Accessories of this generic type of device may include transmission media for acoustically coupling the transducer to the body surface, such as acoustic gel, paste, or a flexible fluid container.

(b) *Classification.* Class II.

**§ 892.1600 Angiographic x-ray system.**

(a) *Identification.* An angiographic x-ray system is a device intended for radiologic visualization of the heart, blood vessels, or lymphatic system during or after injection of a contrast medium. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1610 Diagnostic x-ray beam-limiting device.**

(a) *Identification.* A diagnostic x-ray beam-limiting device is a device such as a collimator, a cone, or an aperture intended to restrict the dimensions of a

diagnostic x-ray field by limiting the size of the primary x-ray beam.

(b) *Classification.* Class II.

**§ 892.1620 Cine or spot fluorographic x-ray camera.**

(a) *Identification.* A cine or spot fluorographic x-ray camera is a device intended to photograph diagnostic images produced by x-rays with an image intensifier.

(b) *Classification.* Class II.

**§ 892.1630 Electrostatic x-ray imaging system.**

(a) *Identification.* An electrostatic x-ray imaging system is a device intended for medical purposes that uses an electrostatic field across a semiconductive plate, a gas-filled chamber, or other similar device to convert a pattern of x-radiation into an electrostatic image and, subsequently, into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1640 Radiographic film marking system.**

(a) *Identification.* A radiographic film marking system is a device intended for medical purposes to add identification and other information onto radiographic film by means of exposure to visible light.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48444, Nov. 20, 1990, as amended at 59 FR 63015, Dec. 7, 1994]

**§ 892.1650 Image-intensified fluoroscopic x-ray system.**

(a) *Identification.* An image-intensified fluoroscopic x-ray system is a device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1660 Non-image-intensified fluoroscopic x-ray system.**

(a) *Identification.* A non-image-intensified fluoroscopic x-ray system is a device intended to be used to visualize anatomical structures by using a fluorescent screen to convert a pattern of x-radiation into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1670 Spot-film device.**

(a) *Identification.* A spot-film device is an electromechanical component of a fluoroscopic x-ray system that is intended to be used for medical purposes to position a radiographic film cassette to obtain radiographs during fluoroscopy.

(b) *Classification.* Class II.

**§ 892.1680 Stationary x-ray system.**

(a) *Identification.* A stationary x-ray system is a permanently installed diagnostic system intended to generate and control x-rays for examination of various anatomical regions. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1700 Diagnostic x-ray high voltage generator.**

(a) *Identification.* A diagnostic x-ray high voltage generator is a device that is intended to supply and control the electrical energy applied to a diagnostic x-ray tube for medical purposes. This generic type of device may include a converter that changes alternating current to direct current, filament transformers for the x-ray tube, high voltage switches, electrical protective devices, or other appropriate elements.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996]

**§ 892.1710 Mammographic x-ray system.**

(a) *Identification.* A mammographic x-ray system is a device intended to be used to produce radiographs of the breast. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1720 Mobile x-ray system.**

(a) *Identification.* A mobile x-ray system is a transportable device system intended to be used to generate and control x-ray for diagnostic procedures. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1730 Photofluorographic x-ray system.**

(a) *Identification.* A photofluorographic x-ray system is a device that includes a fluoroscopic x-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1740 Tomographic x-ray system.**

(a) *Identification.* A tomographic x-ray system is an x-ray device intended to be used to produce radiologic images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1750 Computed tomography x-ray system.**

(a) *Identification.* A computed tomography x-ray system is a diagnostic x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This generic

type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

**§ 892.1760 Diagnostic x-ray tube housing assembly.**

(a) *Identification.* A diagnostic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers or other appropriate components.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996]

**§ 892.1770 Diagnostic x-ray tube mount.**

(a) *Identification.* A diagnostic x-ray tube mount is a device intended to support and to position the diagnostic x-ray tube housing assembly for a medical radiographic procedure.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996]

**§ 892.1820 Pneumoencephalographic chair.**

(a) *Identification.* A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (x-ray imaging of the brain).

(b) *Classification.* Class II.

**§ 892.1830 Radiologic patient cradle.**

(a) *Identification.* A radiologic patient cradle is a support device intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996]

**§ 892.1840 Radiographic film.**

(a) *Identification.* Radiographic film is a device that consists of a thin sheet of radiotransparent material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

**§ 892.1850 Radiographic film cassette.**

(a) *Identification.* A radiographic film cassette is a device intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film.

(b) *Classification.* Class II.

**§ 892.1860 Radiographic film/cassette changer.**

(a) *Identification.* A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between x-ray exposures and to position it during the exposure.

(b) *Classification.* Class II.

**§ 892.1870 Radiographic film/cassette changer programmer.**

(a) *Identification.* A radiographic film/cassette changer programmer is a device intended to be used to control the operations of a film or cassette changer during serial medical radiography.

(b) *Classification.* Class II.

**§ 892.1880 Wall-mounted radiographic cassette holder.**

(a) *Identification.* A wall-mounted radiographic cassette holder is a device that is a support intended to hold and position radiographic cassettes for a radiographic exposure for medical use.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996]

**§ 892.1890 Radiographic film illuminator.**

(a) *Identification.* A radiographic film illuminator is a device containing a visible light source covered with a translucent front that is intended to be used to view medical radiographs.

(b) *Classification.* Class I.

[55 FR 48444, Nov. 20, 1990]

**§ 892.1900 Automatic radiographic film processor.**

(a) *Identification.* An automatic radiographic film processor is a device intended to be used to develop, fix, wash, and dry automatically and continuously film exposed for medical purposes.

(b) *Classification.* Class II.

[55 FR 48444, Nov. 20, 1990]

**§ 892.1910 Radiographic grid.**

(a) *Identification.* A radiographic grid is a device that consists of alternating radiolucent and radiopaque strips intended to be placed between the patient and the image receptor to reduce the amount of scattered radiation reaching the image receptor.

(b) *Classification.* Class I.

**§ 892.1920 Radiographic head holder.**

(a) *Identification.* A radiographic head holder is a device intended to position the patient's head during a radiographic procedure.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807. The device is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

**§ 892.1940 Radiologic quality assurance instrument.**

(a) *Identification.* A radiologic quality assurance instrument is a device intended for medical purposes to measure a physical characteristic associated with another radiologic device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807. The device is exempt from the cur-

rent good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

**§ 892.1950 Radiographic anthropomorphic phantom.**

(a) *Identification.* A radiographic anthropomorphic phantom is a device intended for medical purposes to simulate a human body for positioning radiographic equipment.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807. The device is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

**§ 892.1960 Radiographic intensifying screen.**

(a) *Identification.* A radiographic intensifying screen is a device that is a thin radiolucent sheet coated with a luminescent material that transforms incident x-ray photons into visible light and intended for medical purposes to expose radiographic film.

(b) *Classification.* Class I.

**§ 892.1970 Radiographic ECG/respirator synchronizer.**

(a) *Identification.* A radiographic ECG/respirator synchronizer is a device intended to be used to coordinate an x-ray film exposure with the signal from an electrocardiograph (ECG) or respirator at a predetermined phase of the cardiac or respiratory cycle.

(b) *Classification.* Class I.

[55 FR 48444, Nov. 20, 1990]

**§ 892.1980 Radiologic table.**

(a) *Identification.* A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures

in subpart E of part 807 of this chapter subject to § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 63 FR 59231, Nov. 3, 1998]

**§ 892.1990 Transilluminator for breast evaluation.**

(a) *Identification.* A transilluminator, also known as a diaphanoscope or lightscanner, is an electrically powered device that uses low intensity emissions of visible light and near-infrared radiation (approximately 700–1050 nanometers (nm)), transmitted through the breast, to visualize translucent tissue for the diagnosis of cancer, other conditions, diseases, or abnormalities.

(b) *Classification.* Class III (premarket approval).

(c) *Date premarket approval (PMA) or notice of completion of a product development protocol (PDP) is required.* The effective date of the requirement for premarket approval has not been established. See § 892.3.

[60 FR 36639, July 18, 1995]

**§ 892.2010 Medical image storage device.**

(a) *Identification.* A medical image storage device is a device that provides electronic storage and retrieval functions for medical images. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device stores images without performing irreversible data compression.

[63 FR 23387, Apr. 29, 1998; 63 FR 44998, Aug. 24, 1998]

**§ 892.2020 Medical image communications device.**

(a) *Identification.* A medical image communications device provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, interfaces, and a communications protocol.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when the device

transfers images without performing irreversible data compression.

[63 FR 23387, Apr. 29, 1998; 63 FR 44998, Aug. 24, 1998]

**§ 892.2030 Medical image digitizer.**

(a) *Identification.* A medical image digitizer is a device intended to convert an analog medical image into a digital format. Examples include systems employing video frame grabbers, and scanners which use lasers or charge-coupled devices.

(b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std.).

[63 FR 23387, Apr. 29, 1998]

**§ 892.2040 Medical image hardcopy device.**

(a) *Identification.* A medical image hardcopy device is a device that produces a visible printed record of a medical image and associated identification information. Examples include multifunction cameras and laser printers.

(b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

[63 FR 23387, Apr. 29, 1998]

**§ 892.2050 Picture archiving and communications system.**

(a) *Identification.* A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

(b) *Classification.* Class II (special controls; voluntary standards—Digital

Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

[63 FR 23387, Apr. 29, 1998]

### Subparts C–E [Reserved]

### Subpart F—Therapeutic Devices

#### § 892.5050 Medical charged-particle radiation therapy system.

(a) *Identification.* A medical charged-particle radiation therapy system is a device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II. When intended for use as a quality control system, the film dosimetry system (film scanning system) included as an accessory to the device described in paragraph (a) of this section, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

[53 FR 1567, Jan. 20, 1988, as amended at 64 FR 1125, Jan. 8, 1999]

#### § 892.5300 Medical neutron radiation therapy system.

(a) *Identification.* A medical neutron radiation therapy system is a device intended to generate high-energy neutrons for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment support, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

#### § 892.5650 Manual radionuclide applicator system.

(a) *Identification.* A manual radionuclide applicator system is a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation

therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) *Classification.* Class I.

#### § 892.5700 Remote controlled radionuclide applicator system.

(a) *Identification.* A remote controlled radionuclide applicator system is an electromechanical or pneumatic device intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) *Classification.* Class II.

#### § 892.5710 Radiation therapy beam-shaping block.

(a) *Identification.* A radiation therapy beam-shaping block is a device made of a highly attenuating material (such as lead) intended for medical purposes to modify the shape of a beam from a radiation therapy source.

(b) *Classification.* Class II.

#### § 892.5730 Radionuclide brachytherapy source.

(a) *Identification.* A radionuclide brachytherapy source is a device that consists of a radionuclide which may be enclosed in a sealed container made of gold, titanium, stainless steel, or platinum and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy.

(b) *Classification.* Class II.

#### § 892.5740 Radionuclide teletherapy source.

(a) *Identification.* A radionuclide teletherapy source is a device consisting of a radionuclide enclosed in a sealed container. The device is intended for radiation therapy, with the radiation source located at a distance from the patient's body.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 59 FR 63015, Dec. 7, 1994]

**§ 892.5750 Radionuclide radiation therapy system.**

(a) *Identification*. A radionuclide radiation therapy system is a device intended to permit an operator to administer gamma radiation therapy, with the radiation source located at a distance from the patient's body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts (including beam-limiting devices), and accessories.

(b) *Classification*. Class II.

**§ 892.5770 Powered radiation therapy patient support assembly.**

(a) *Identification*. A powered radiation therapy patient support assembly is an electrically powered adjustable couch intended to support a patient during radiation therapy.

(b) *Classification*. Class II.

**§ 892.5780 Light beam patient position indicator.**

(a) *Identification*. A light beam patient position indicator is a device that projects a beam of light (incoherent light or laser) to determine the alignment of the patient with a radiation beam. The beam of light is intended to be used during radiologic procedures to ensure proper positioning of the patient and to monitor alignment of the radiation beam with the patient's anatomy.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996]

**§ 892.5840 Radiation therapy simulation system.**

(a) *Identification*. A radiation therapy simulation system is a fluoroscopic or radiographic x-ray system intended for use in localizing the volume to be exposed during radiation therapy and

confirming the position and size of the therapeutic irradiation field produced. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification*. Class II.

**§ 892.5900 X-ray radiation therapy system.**

(a) *Identification*. An x-ray radiation therapy system is a device intended to produce and control x-rays used for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification*. Class II.

**§ 892.5930 Therapeutic x-ray tube housing assembly.**

(a) *Identification*. A therapeutic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing intended for use in radiation therapy. This generic type of device may include high-voltage and filament transformers or other appropriate components when contained in radiation-shielded housing.

(b) *Classification*. Class II.

## Subpart G—Miscellaneous Devices

**§ 892.6500 Personnel protective shield.**

(a) *Identification*. A personnel protective shield is a device intended for medical purposes to protect the patient, the operator, or other persons from unnecessary exposure to radiation during radiologic procedures by providing an attenuating barrier to radiation. This generic type of device may include articles of clothing, furniture, and movable or stationary structures.

(b) *Classification*. Class I. If the device's labeling specifies the lead equivalence, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 61 FR 1125, Jan. 16, 1996]

**PART 895—BANNED DEVICES****Subpart A—General Provisions**

Sec.

- 895.1 Scope.
- 895.20 General.
- 895.21 Procedures for banning a device.
- 895.22 Submission of data and information by the manufacturer, distributor, or importer.
- 895.25 Labeling.
- 895.30 Special effective date.

**Subpart B—Listing of Banned Devices**

895.101 Prosthetic hair fibers.

AUTHORITY: 21 U.S.C. 352, 360f, 360h, 360i, 371.

SOURCE: 44 FR 29221, May 18, 1979, unless otherwise noted.

**Subpart A—General Provisions****§ 895.1 Scope.**

(a) This part describes the procedures by which the Commissioner may institute proceedings to make a device intended for human use that presents substantial deception or an unreasonable and substantial risk of illness or injury a banned device.

(b) This part applies to any “device”, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (act) that is intended for human use.

(c) A device that is made a banned device in accordance with this part is adulterated under section 501(g) of the act. A restricted device that is banned may also be misbranded under section 502(q) of the act.

(d) Although this part does not cover devices intended for animal use, the manufacturer, distributor, importer, or any other person(s) responsible for the labeling of the device that is banned cannot avoid the ban by relabeling the device for veterinary use. A device that has been banned from human use but that also has a valid veterinary use may be marketed for use as a veterinary device only under the following conditions: The device shall comply with all requirements applicable to veterinary devices under the Federal Food, Drug, and Cosmetic Act and this chapter, and the label for the device shall bear the following statement: “For Veterinary Use Only. Caution:

Federal law prohibits the distribution of this device for human use.” A device so labeled, however, that is determined by the Food and Drug Administration to be intended for human use, will be considered to be a banned device. In determining whether such a device is intended for human use, the Food and Drug Administration will consider, among other things, the ultimate destination of the device.

**§ 895.20 General.**

The Commissioner may initiate a proceeding to make a device a banned device whenever the Commissioner finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury that the Commissioner determines cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, or by a change in advertising if the device is a restricted device.

[44 FR 29221, May 18, 1979, as amended at 57 FR 58405, Dec. 10, 1992]

**§ 895.21 Procedures for banning a device.**

(a) Before initiating a proceeding to make a device a banned device, the Commissioner shall find that the continued marketing of the device presents a substantial deception or an unreasonable and substantial risk of illness or injury.

(1) In determining whether the deception or risk of illness or injury is substantial, the Commissioner will consider whether the deception or risk posed by continued marketing of the device, or continued marketing of the device as presently labeled, is important, material, or significant in relation to the benefit to the public health from its continued marketing.

(2) In determining whether a device is deceptive, the Commissioner will consider whether users of the device may be deceived or otherwise harmed by the device. The Commissioner is not required to determine that there was an intent on the part of the manufacturer, distributor, importer, or any other responsible person(s) to mislead or otherwise harm users of the device or that